

2-14-05

IFw

PATENT  
Docket No. 546322000302

**CERTIFICATE OF EXPRESS MAIL**

I hereby certify that this paper or fee is being deposited with the United States Postal Service under 37 C.F.R. § 1.10 via Express Mail Label No. EV 470 627 053 US on the date indicated above and is addressed to: **MAIL STOP: AMENDMENT**, Commissioner for Patents, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Date of Deposit: February 11, 2005

Lilia Olsen

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Michael W. GRAHAM et al.

Serial No.: 10/759,841

Filing Date: January 15, 2004

For: SYNTHETIC GENES AND GENETIC  
CONSTRUCTS

Examiner: Not Yet Assigned

Group Art Unit: 1632

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

**MAIL STOP: AMENDMENT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial Number US 10/346,853, filed January 17, 2003, and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R.

§1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the application.

This application includes in its chain of priority U.S. application 09/100,812, now issued U.S. Patent 6,573,099. The Examiner's attention is directed to the preliminary amendment filed in US 2003/0056235 A1, which relates to U.S. Patent 6,573,099. U.S. Patent 6,573,099 is the subject of ongoing patent litigation: Benitec Australia Ltd. v. Nucleonics, Inc., Ambion, Inc., and GenScript, Inc., Civil Action No. 04-174 (JFF), U.S. District Court for the District of Delaware. As of February 2004, the litigation has been dismissed with respect to defendants Ambion, Inc. and GenScript, Inc. The litigation is ongoing with respect to Benitec Australia Ltd. and Nucleonics, Inc. The Judge in the ongoing litigation recently denied Nucleonics Inc.'s Motion to Dismiss under 271(e).

Applicants respectfully direct the attention of the Examiner to the titles of the 4548 references (without full copies of the references) attached to this Information Disclosure Statement as Exhibit A. This list was provided to the Applicants by defendant Genscript, Inc. prior to Genscript's dismissal from the ongoing patent litigation suit. Applicants have not separately obtained or reviewed any of the 4548 references (even to confirm that the list actually sets out 4548 references), nor have they examined all of the titles, except to the extent that any of the references have already been in the possession of the Applicants (in which case such reference(s) would have been provided to the Examiner if material and not cumulative with references already provided). Applicants have no reason to believe that the references in the list are material to the claimed invention and have no reason to believe that, even if material, any of the references would not be cumulative in light of the over 270 references already submitted during the prosecution of this patent application, other than the submission by the defendant. The Examiner is requested to review the enclosed list of references.

Applicants further direct the attention of the Examiner to the titles of the additional references (without full copies of the references) attached to this Information Disclosure Statement as Exhibit B. This list was provided to the Applicants by defendant Nucleonics, Inc. in the litigation as art that Nucleonics, Inc. may rely on in the ongoing litigation. Applicants have not separately obtained or reviewed any of the references listed on Exhibit B, nor have they examined all of the titles, except to the extent that any of the references have already been in the possession of the Applicants (in which case such reference(s) would have been provided to the Examiner if material and not cumulative with references already provided). Applicants have no reason to believe that the references in the list are material to the claimed invention and have no reason to believe that, even if material, any of the references would not be cumulative in light of the over 270 references already submitted during the prosecution of this patent application, other than the submission by the defendant. The Examiner is requested to review the enclosed list of references.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ **Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.**
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \_\_ is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_ is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search

has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 546322000302. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: February 11, 2005

Respectfully submitted,

By: Michael R. Ward  
Michael R. Ward  
Registration No. 38,651

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Please type a plus sign inside this box

PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/759,841	
	Filing Date	January 15, 2004	
	First Named Inventor	Michael Wayne GRAHAM	
	Group Art Unit	1632	
	Examiner Name	Not Yet Assigned	
Total Number of Pages in This Submission	407	Attorney Docket Number	546322000302

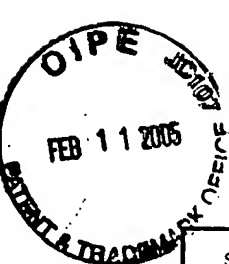
ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply--Preliminary Amendment - 3 pgs	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below)
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	1. PTO-SB/08a/b - 2 pgs with 26 listed refs - no copies attached
<input checked="" type="checkbox"/> Information Disclosure Statement- 5 pgs	<input type="checkbox"/> Request for Refund	2. EXH A (379 pgs) attached
<input type="checkbox"/> PTO-1449 - 6 pgs w/89 references attached	<input type="checkbox"/> CD, Number of CD(s) _____	3. EXH B (20 pgs) attached
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application	Remarks	Return Receipt Postcard
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual Name	MORRISON & FOERSTER LLP MICHAEL R. WARD (Reg. No. 38,651)	CUSTOMER NO. 20872
Signature		
Date	February 11, 2004	

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Dated: February 11, 2005	By  (LILIA OLSEN)

SF-1646822

EV470627053US



<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/759,841
				Filing Date	January 15, 2004
				First Named Inventor	Michael W. GRAHAM
				Art Unit	1632
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	546322000302

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US 4,766,072	08-23-1988	Jendrisak et al.	
	AB	US 5,190,931	03-02-1993	Inouye	
	AC	US 5,208,149	05-04-1993	Inouye	
	AD	US 5,272,065	12-21-1993	Inouye et al.	
	AE	US 2003/0056235 A1 with amendments	03-20-2003	Fire et al.	
	AF	US 2004/0064842 A1	04-01-2004	Graham et al.	
	AG	US 2004/0237145 A1	11-25-2004	Graham et al.	
	AH	US 2004/0266005 A1	12-30-2004	Graham et al.	
	AI	US 09/646,807		Graham et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	WO 97/44450	11-27-1997		WO	
	BB	WO 03/022052	03-20-2003		WO	
	BC	WO 03/056012	07-10-2003		WO	

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	COHLI ET AL. (1994) "Inhibition of HIV-1 multiplication in a human CD4+ lymphocytic cell line expressing antisense and sense RNA molecules containing HIV-1 packaging signal and Rev response element(s)" Antisense Research and Development 4: 19-26.	
	CB	FIRE ET AL. (1991) "Production of Antisense RNA Leads to Effective and Specific Inhibition of Gene Expression in C. Elegans Muscle" Development, 113(2): 503-514.	
	CC	FRASER ET AL. (1996) "Effects of c-myc first exons and 5' synthetic hairpins on RNA translation in oocytes and early embryos of Xenopus laevis" Oncogene 12(6):1223-30.	
	CD	Hungarian Patent Office Search Report mailed July 13, 2004, for Hungary patent application no. P0101225, 1 page.	
	CE	KIBLER ET AL. (1997) "Double Stranded RNA is a Trigger for Apoptosis in Vaccinia Virus Infected Cells" Journal of Virology, 71(3): 1992-2003.	
	CF	KOZAK (1989) "Circumstances and mechanisms of inhibition of translation by secondary structure in eucaryotic mRNAs" Mol. Cell. Biol. 9:5134-5142.	

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/759,841
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				Art Unit	1632
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Sheet	2	of	2	Attorney Docket Number	546322000302

	CG	LIEBHABER ET AL. (1992) "Translation inhibition by an mRNA coding region secondary structure is determined by its proximity to the AUG initiation codon" J. Mol. Biol. 226:609-621.	
	CH	LINGELBACH ET AL. (1988) "An extended RNA/RNA duplex structure within the coding region of mRNA does not block translational elongation" Nuc. Acids Res. 16 3405-3414.	
	CI	LOOMIS ET AL. (1991) "Antisense RNA inhibition of expression of a pair of tandemly repeated genes results in a delay in cell-cell adhesion in Dictyostelium" Antisense Res. Dev.1:255-260.	
	CJ	MIKOSHIBA ET AL. (1991) "Molecular biology of myelin basic protein: gene rearrangement and expression of anti-sense RNA in myelin-deficient mutants" Comp. Biochem. Physiol. 98:51-61.	
	CK	OKANO ET AL. (1991) "Myelin basic protein gene and the function of antisense RNA in its repression in myelin-deficient mutant mouse" J. Neurochem. 56:560-567.	
	CL	PELLETIER ET AL. (1985) "Insertion mutagenesis to increase secondary structure within the 5' noncoding region of a eukaryotic mRNA reduces translational efficiency" Cell, 40:515-526.	
	CM	WATSON (1988) "A new revision of the sequence of plasmid pBR322" Gene 70:399-403.	
	CN	WEAVER ET AL. (1981) "Introduction by molecular cloning of artifactual inverted sequences at the 5' terminus of the sense strand of bovine parathyroid hormone cDNA" PNAS 78: 4073-4077.	

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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